



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,926	09/09/2003	Paul D. Corl	33483/US/ENB	3127

75149 7590 03/11/2008
Dorsey & Whitney LLP
US Bank Center
1420 Fifth Avenue
Suite 3400
Seattle, WA 98101-4010

EXAMINER

TOTH, KAREN E

ART UNIT	PAPER NUMBER
----------	--------------

3735

MAIL DATE	DELIVERY MODE
-----------	---------------

03/11/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.		Applicant(s)	
	10/658,926		CORL ET AL.	
	Examiner		Art Unit	
	KAREN E. TOTH		3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-29 and 56-73 is/are pending in the application.
- 4a) Of the above claim(s) 66 and 67 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 70-73 is/are allowed.
- 6) ☒ Claim(s) 25-29, 56-65, 68 and 69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12/10/07</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

2. Claims 25, 26, 28, 29, 63, and 64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel (US Patent Application Publication 2003/0050547) in view of Markle (US Patent 5596988).

Regarding claim 25, Lebel discloses a probe comprising a cannula (element 12) with proximal (element 14) and distal (element 18) extremities, where the distal extremity is adapted to be inserted in a patient's blood vessel (paragraph [0030]) and contains an oxygen sensor assembly that provides an electrical signal when the cannula is disposed in the blood (element 20; paragraphs [0030], [0032]), and where the proximal extremity carries a connector (element 16); the distal extremity is adapted to slidably travel through an introducer when being inserted into the vessel (figure 9; step 110; paragraphs [0058]-[0059]), and the cannula and connector are sized such that the introducer may be slid off the proximal extremity and cannula after the distal extremity has been inserted (figure 9; step 112; paragraphs [0058]-[0059]). The Examiner notes that, though an introducer is mentioned in the claim, it is not actually part of the claimed apparatus, and the probe of Lebel merely needs to be able to work with any device used as an introducer. Lebel does not disclose a preferred diameter range for the cannula, nor a carbon dioxide sensor in addition to the oxygen sensor.

Art Unit: 3735

Markle teaches a probe for ascertaining characteristics of blood comprising a cannula having a diameter between 0.010 and 0.035 inches (column 5, lines 62-63), and a plurality of gas sensors, including those for carbon dioxide and oxygen in the distal extremity of the cannula (column 6 lines 1-3), in order to accurately monitor a patient's blood characteristics in small vessels. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel with an additional gas sensor for oxygen, and sized the system to fit into small vessels, having an external diameter between 0.010 and 0.035 inches, as taught by Markle, in order to monitor multiple components of blood in small vessels.

Regarding claim 26, Lebel further discloses using an introducer with the device (paragraphs [0058]-[0059]).

Regarding claims 28 and 29, Lebel further discloses the connector having a cylindrical portion (figure 1) and an electrical contact (paragraph [0031]), and the probe having a conductor extending from the electrical contact to the sensor and seated flush with the cylindrical portion (element 62; paragraphs [0042] and [0046]).

Regarding claims 63 and 64, Lebel discloses using gas-permeable material to form the cannula (element 66; paragraphs [0044], [0054]).

3. Claim 27 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, as applied to claims 25, 26, 28, 29, 63, and 64 above, and further in view of Schulman (US Patent 5497772).

Lebel in view of Markle discloses all the elements of the claimed invention, as described above, except for the introducer being a needle. Schulman teaches a system for implanting a blood component sensor comprising an introducer needle that is used to place a sensor probe (column 10, lines 10-24), in order to ease the insertion of the sensor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle with an introducer needle, as taught by Schulman, in order to ease insertion of the sensor.

4. Claims 56-58 and 60-61 rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, as applied to claims 25, 26, 28, 29, 63, and 64 above, and further in view of Cheney (US Patent 5391250).

Regarding claim 56, Lebel in view of Markle discloses all the elements of the claimed invention, as disclosed above, except for the probe comprising a flex circuit extending through the cannula, having a distal portion with two electrodes, and conductors running between a proximal end of the cannula and the electrodes, where the electrodes are at least part of the gas sensor assembly. Lebel further discloses the gas sensor comprising electrodes (elements 36) on a substrate (element 30), with conductors that are used to connect the electrodes to proximal portions of the sensor (elements 44). Lebel does not disclose the substrate being flexible (that is, the sensor assembly being a flex circuit).

Cheney discloses forming a gas sensor assembly using a flex circuit (element 10) comprising a distal portion with two electrodes (elements 24) and conductors

Art Unit: 3735

(elements 14) connecting the electrodes to a proximal portion of the device (figure 1), so that the sensor is both accurate and durable. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle with a flex circuit for sensing gas, as taught by Cheney, so that the sensor is both accurate and durable.

Regarding claims 57 and 58, Lebel further discloses a sealed chamber in the cannula containing an electrolyte solution and the electrodes (paragraph [0054]-[0056]).

Regarding claim 60, Cheney further discloses the proximal portion of the flex circuit serving as a connector (elements 26), in order to reduce the number of components and electrical connections in the system. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Markle and Cheney with the proximal end of the flex circuit serving as the connector, as taught by Cheney, in order to reduce the number of components and connections in the system.

Regarding claim 61, Lebel further discloses the electrodes being pads formed on the exposed surface of the circuit (figure 2A).

5. Claim 59 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle and Cheney, as applied to claims 56-58 and 60-61 above, and further in view of Schulman (US Patent Application Publication 2001/0051768).

Lebel in view of Markle and Cheney discloses all the elements of the claimed invention, as described above, except for the probe further comprising a second sealed chamber housing two additional electrodes and an electrolyte solution.

Schulman teaches an implantable probe for sensing components of blood comprising a plurality of sealed chambers (in this case, the combination of a “sensor assembly” and window), each having two electrodes (elements 12, 14, 16, 18) and an electrolyte solution (element 22) (paragraphs [0026]-[0027], 0031, [0034-0037], [0062]), in order to allow sensing from a variety of areas within the patient’s body without requiring multiple probes. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle and Cheney with an additional chamber having electrodes and an electrolyte solution, as taught by Schulman, in order to allow sensing from a variety of areas within the patient’s body without requiring multiple probes.

6. Claim 62 rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle and Cheney, as applied to claims 56-58 and 60-61 above, and further in view of Pantages (US Patent Application Publication 2001/0029337).

Lebel in view of Markle and Cheney discloses all the elements of the claimed invention, as described above, except for the probe comprising adhesive to hold the flex circuit in place in the cannula. Pantages teaches an implantable blood characteristic probe comprising a flex circuit held in place in a cannula using adhesive (paragraph [0084]), in order to ensure that the flex circuit does not move. It would have been

Art Unit: 3735

obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Markle and Cheney with adhesive securing the flex circuit within the cannula, as taught by Pantages, in order to ensure that it does not move.

7. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, as applied to claims 25, 26, 28, 29, 63, and 64 above, and further in view of Kirsch (US Patent 6503225).

Lebel in view of Markle discloses all the elements of the claimed invention, as described above, except for the gas permeable material being polymethylpentene. Kirsch teaches an implantable probe system having a gas permeable coating of polymethylpentene (column 4, lines 43-45), since use of polymethylpentene as a gas permeable polymer coating is well known in the implantable probe art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Markle with a polymethylpentene coating, as taught by Kirsch, since it is a well-known gas permeable polymer coating material.

8. Claims 68 and 69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle, as applied to claims 25, 26, 28, 29, 63, and 64 above, and further in view of Webber (US Patent 6166614).

Lebel in view of Markle discloses all the elements of the claimed invention, as described above, except for the system further comprising a display module with a

Art Unit: 3735

connector for connecting to the probe's connector, allowing communication between the probe and display, and where the display module includes a band that makes it adaptable for securing to a patient's wrist.

Webber teaches an implantable probe system comprising a display module (element 22) that connects to and communicates with the implantable blood probe (elements 23, 24, 51), and comprises a band (element 28) that allows the display to be mounted on the patient's arm in a location of the user's choosing, such as the wrist (figure 1), in order to provide as much mobility to the patient as possible while still accurately monitoring the blood gas. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle with a display module connected to the connector of the probe and secured to the patient's wrist, as taught by Webber, in order to provide mobility while monitoring blood gas.

9. Claim 70 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle and Kirsch.

Lebel discloses a probe comprising a cannula (element 12) with proximal (element 14) and distal (element 18) extremities, where the distal extremity is adapted to be inserted in a patient's blood vessel (paragraph [0030]) and contains an oxygen sensor assembly that provides an electrical signal when the cannula is disposed in the blood (element 20; paragraphs [0030], [0032]), and where the proximal extremity carries a connector (element 16); the distal extremity is adapted to slidably travel through an

Art Unit: 3735

introducer when being inserted into the vessel (figure 9; step 110; paragraphs [0058]-[0059]), and the cannula and connector are sized such that the introducer may be slid off the proximal extremity and cannula after the distal extremity has been inserted (figure 9; step 112; paragraphs [0058]-[0059]). Lebel does not teach the gas sensing assembly comprising both oxygen and carbon dioxide sensors, nor the area in that vicinity being composed of polymethylpentene.

Markle teaches a probe for ascertaining characteristics of blood comprising a catheter and a plurality of gas sensors, including those for carbon dioxide and oxygen in the distal extremity of the cannula (column 6 lines 1-3), in order to accurately monitor a patient's blood characteristics. Kirsch teaches an implantable probe system having a gas permeable coating of polymethylpentene (column 4, lines 43-45), since use of polymethylpentene as a gas permeable polymer coating is well known in the implantable probe art. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel with an additional gas sensor for oxygen, as taught by Markle, in order to simultaneously monitor multiple components of blood, and with a polymethylpentene coating, as taught by Kirsch, since it is a well-known gas permeable polymer coating material.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel.

Art Unit: 3735

10. Claims 71-73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lebel in view of Markle and Kirsch, as applied to claim 70 above, and further in view of Cheney.

Regarding claim 71, Lebel in view of Markle and Kirsch discloses all the elements of the claimed invention, as disclosed above, except for the probe comprising a flex circuit extending through the cannula, having a distal portion with two electrodes, and conductors running between a proximal end of the cannula and the electrodes, where the electrodes are at least part of the gas sensor assembly. Lebel further discloses the gas sensor comprising electrodes (elements 36) on a substrate (element 30), with conductors that are used to connect the electrodes to proximal portions of the sensor (elements 44). Lebel does not disclose the substrate being flexible (that is, the sensor assembly being a flex circuit).

Cheney discloses forming a gas sensor assembly using a flex circuit (element 10) comprising a distal portion with two electrodes (elements 24) and conductors (elements 14) connecting the electrodes to a proximal portion of the device (figure 1), so that the sensor is both accurate and durable. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the system of Lebel in view of Markle and Kirsch with a flex circuit for sensing gas, as taught by Cheney, so that the sensor is both accurate and durable.

Regarding claim 72, Cheney further discloses the proximal portion of the flex circuit serving as a connector (elements 26), in order to reduce the number of components and electrical connections in the system. It would have been obvious to

Art Unit: 3735

one of ordinary skill in the art at the time the invention was made to have made the probe of Lebel in view of Markle, Kirsch, and Cheney with the proximal end of the flex circuit serving as the connector, as taught by Cheney, in order to reduce the number of components and connections in the system.

Regarding claim 73, Lebel further discloses the electrodes being pads formed on the exposed surface of the circuit (figure 2A).

Response to Arguments

11. Applicant's arguments with respect to claims 25-29, 56-65, 68, and 69 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US Patent 4016864 to Sielaff, which discloses a similar invention.

US Patent Application Publication 2003/0055353 to Webber, which discloses similar inventions.

US Patent 6306103 to Tyler, which discloses similar inventions.

US Patent 4832034 to Pizziconi, which discloses similar inventions.

US Patent 3893448 to Brantigan, which discloses similar inventions.

US Patent Application Publication 2006/0235314 to Migliuolo, which discloses similar inventions.

US Patent 6607477 to Longton, which discloses similar inventions.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KAREN E. TOTH whose telephone number is (571)272-6824. The examiner can normally be reached on Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert L. Nasser Jr/
Primary Examiner, Art Unit 3735

/K. E. T./
Examiner, Art Unit 3735